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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,703	10/09/2006	Susanne Lang-Fugmann	9741-014-999	9359
20582	7590	07/03/2008	EXAMINER	
JONES DAY			KASSA, TIGABU	
222 East 41st Street				
New York, NY 10017-6702				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/554,703	Applicant(s) LANG-FUGMANN, SUSANNE	
	Examiner TIGABU KASSA	Art Unit 4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Claims

This application is a 371 of PCT/EP04/00597 filed on 01/24/2004, which is filled at national stage 10/09/2006. Claims 1-13 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Priority

The earliest effective filing date afforded for the instantly claimed invention, has been determined to be 01/24/2004, the filing date of the PCT/EP04/00597.

Information Disclosure Statement

NO information disclosure statement (IDS) is submitted with this application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention..

Claim 11 contains the trademark/trade name Abafungin. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a

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trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe one compound which has an antifungal activity and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 7-9, and 11-13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ippen et al. (US Patent No. 4,956,370, Issued on September 11, 1990) as evidenced by (<http://www.thefreedictionary.com/polyethylene+glycol>, checked June 24, 2008).

3. Instant claims 1 and 2 recite a pharmaceutical, antimycotically active nail lacquer for the treatment or prophylaxis of fungal infections of nails and skin comprising an optionally substituted 2-aminothiazole.

4. Ippen et al. (US Patent No. 4,956,370) discloses a pharmaceutical composition useful for combating mycoses comprising substituted 2-aminothiazole and other pharmaceutical excipients (column 1, lines 20-68, column 2, lines 1-21, column 146, line 46-49, and see Abstract). Ippen et al. (US Patent No. 4,956,370) discloses that the pharmaceutical preparation could be in the form of tablets, coated tablets, capsules, pills, granules, suppositories, solutions, suspensions, emulsions, pastes, ointments, gels, creams, lotions, powders, or sprays (column 19, lines 62-66). It is examiner's position that the pharmaceutical composition described by Ippen et al. (US

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Patent No. 4,956,370) as being able to be prepared in various forms are cable of being nail lacquer compositions, as a result Ippen et al. (US Patent No. 4,956,370) anticipates instant claims 1 and 2.

5. Instant claims 7-9 recite pharmaceutical, antimycotically active nail lacquer also comprises a plasticizer, and at least one solvent from the list recited in instant claim 9, respectively.

6. Ippen et al. (US Patent No. 4,956,370) discloses the pharmaceutical composition also comprises a plasticizer such as polyethylene glycols (column 20, line 30) which are known plasticizers in the art and also see (<http://www.thefreedictionary.com/polyethylene+glycol>, checked June 24, 2008), solvents like water, ethyl alcohol, isopropyl alcohol, ethyl acetate etc (column 20, lines 48-51), which reads on instant claims 7-9.

7. Instant claim 11 recites that the antimycotically active ingredient in the composition is Abafungin.

8. Ippen et al. (US Patent No. 4,956,370) also discloses that in the examples section the use of Abafungin (Table A column 141, compound 149) in *in vitro* activity test, which is the structure of Abafungin, which reads on instant claim 11.

9. Instant claims 12 and 13 recite a method for the treatment and prophylaxis of fungal infections respectively.

10. Ippen et al. (US Patent No. 4,956,370) teaches that the pharmaceutical composition can be used for the treatment prevention, amelioration and/or cure of mycoses (column 21, lines 26-27) either dermatomycoses and systemic mycoses (column 19, lines 32-33) which includes nails, specifically also Ippen et al. (US Patent No. 4,956,370) discloses a method of combating

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mycoses through administering the above disclosed pharmaceutical composition (column 146, lines 54-58), which reads on claims 12-13.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

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4. Claims 1, 2, 3, 5-6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ippen et al. (US Patent No. 4,956,370, Issued on September 11, 1990) as evidenced by (<http://www.thefreedictionary.com/polyethylene+glycol>, checked June 24, 2008) in view of Samour et al. (US Patent No. 6,224,887, Issued on May 1, 2001).

5. Instant claims 1 and 2 recite a pharmaceutical, antimycotically active nail lacquer for the treatment or prophylaxis of fungal infections of nails and skin comprising an optionally substituted 2-aminothiazole. In further limitations instant claim 3, 5, and 6 require the pharmaceutical antimycotically active nail lacquer comprises permeation enhancer and polymeric film-forming agent and the film-forming agent being belonging to the group of water-insoluble acrylate polymers or methacrylate polymers and comprises a copolymer that belongs to the compound class of alkylvinylethers, maleic acid anhydride, alkylated poly(vinylpyrrolidones) and ammonium methacrylates respectively.

6. As discussed above Ippen et al. (US Patent No. 4,956,370) teaches all the limitations of instant claim 1 and 2.

This differs from the pharmaceutical antimycotically active nail lacquer of the instant application in that Ippen et al. (US Patent No. 4,956,370) does not teach the incorporation of permeation enhancer as recited in instant claim 3 and the film forming agents as recited in instant claim 5-6.

7. However, Samour et al. (US Patent No. 6,224,887) discloses an antifungal nail lacquer comprising permeation (penetration) enhancing agent (column 3, lines19-21) and polymeric film-forming agent (column 3, line 23). For the types of film forming agents Samour et al. (US Patent No. 6,224,887) also discloses that film forming agents can include acrylate (co)polymers,

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methacrylate (co)polymers, and copolymers of alkyl vinyl ether and maleic anhydride (column 6, line 38-40)

8. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Ippen et al. (US Patent No. 4,956,370) by incorporating permeation enhancing agent and polymeric film-forming agents as taught by Samour et al. (US Patent No. 6,224,887), since the purpose of the permeation enhancing agent is for the penetration of various pharmacologically active principles like through the skin as extensively known and discussed in the art it renders it commonly used mechanism of permeation of pharmaceutical actives in a targeted part of the body. Additionally, the use of polymeric film-forming agents is widely recognized and known routine procedure to optimize and choose various types of film forming agents.

9. Instant claim 10 recites the different % by weight amounts of various components of the pharmaceutical, antimycotically active nail lacquer.

10. As discussed above Ippen et al. (US Patent No. 4,956,370) teaches all the limitations of instant claim 1. This differs from the pharmaceutical antimycotically active nail lacquer of the instant application in that Ippen et al. (US Patent No. 4,956,370) does not teach the incorporation of the other ingredients in the composition recited in instant claim 10.

11. However, Samour et al. (US Patent No. 6,224,887) discloses the an antifungal nail lacquer comprising 5-20 % an antifungal active agent, (column 12, line 25-26), 0.5-35 % enhancer (column 5, line 26), 20-40 % film forming polymer (column 8, line 43), 53% ethanol (column 16, line 55-56), and 2-10% plasticizer (column 9, line 23).

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12. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Ippen et al. (US Patent No. 4,956,370) by incorporating all the other ingredients as taught by Samour et al. (US Patent No. 6,224,887), because the use of all these pharmaceutical additives is known and demonstrated in the art extensively as also illustrated by Samour et al. (US Patent No. 6,224,887) the skilled artisan can follow the same procedure and end up to instant invention with a reasonable success.

9. Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ippen et al. (US Patent No. 4,956,370, Issued on September 11, 1990) as applied to claims 1, 2, 3, 5-6, and 10 above, and further in view of Samour et al. (US Patent No. 6,224,887, Issued on May 1, 2001) and Wohlrab et al. (US Patent No. 6,719,986, filed on September 5, 2001).

10. Instant claims 1 and 2 recite a pharmaceutical, antimycotically active nail lacquer for the treatment or prophylaxis of fungal infections of nails and skin comprising an optionally substituted 2-aminothiazole. In further limitation instant claim 3 and 5 require the pharmaceutical antimycotically active nail lacquer comprises permeation enhancer and polymeric film-forming agent respectively. Additionally, in further limitations instant claim 4 requires hyaluronate lyase as permeation enhancer agent.

11. As discussed above Ippen et al. (US Patent No. 4,956,370) teaches all the limitations of instant claims 1 and 2, further more the other limitations recited in claims 3 and 5 are also addressed above via a combination of teachings by Ippen et al. (US Patent No. 4,956,370) and Samour et al. (US Patent No. 6,224,887). These teachings differ from the instantly recited limitation in instant claim 4 in that they don't teach hyaluronate lyase as the permeation enhancing agent.

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12. However, Wohlrab et al. (US Patent No. 6,719,986) discloses that hyaluronate lyase as a penetration enhancing agent in topical agents (see Abstract).

13. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Ippen et al. (US Patent No. 4,956,370) and Samour et al. (US Patent No. 6,224,887 by incorporating hyaluronate lyase as taught by Wohlrab et al. (US Patent No. 6,719,986) as permeation enhancing agent, since the use of hyaluronate lyase as the permeation enhancing agents is clearly demonstrated that the one skilled in the art can practice the use of it with a reasonable success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

6/26/2008

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4161